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Proposed Maximum Residue Limit PMRL2013-62

Fludioxonil

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on grapes to the product label of Switch 62.5WG Fungicide, containing technical grade fludioxonil and cyprodinil, is acceptable. The specific uses approved in Canada are detailed on the label of Switch 62.5WG Fungicide, *Pest Control Products Act* Registration Number 28189. Based on the maximum residue observed in grapes treated and harvested at the appropriate pre-harvest interval, it was determined that residues of cyprodinil in grapes would be covered under the maximum residue limit currently established for this commodity.

The evaluation of this fludioxonil application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for fludioxonil is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRL, to replace the MRL already established for fludioxonil, is as follows.

Table 1 Proposed Maximum Residue Limit for Fludioxonil

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	2.0[a]	Grapes

ppm = parts per million

[a] The recommended MRL of 2.0 ppm will replace the currently established MRL of 1.0 ppm.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRL proposed for fludioxonil in Canada is the same as the corresponding American tolerance and Codex MRL.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRL

Residue data from field trials conducted in Canada were submitted to support the domestic use of Switch 62.5WG Fungicide on grapes. Fludioxonil was applied to grapes, which were harvested according to the proposed label directions. In addition, a processing study in treated grapes was reassessed in the framework of this petition to determine the potential for concentration of residues of fludioxonil in processed commodities.

Maximum Residue Limit

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for grapes.

TABLE A1 Summary of Field Trial Data Used to Support Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI[a] (days)	Residues (ppm)	
			Min	Max
Grapes	Foliar broadcast/ 464.6–518.6	6–8	0.18	1.1

[a] PHI = preharvest interval

Following the review of all available data, an MRL of 2.0 ppm is recommended to cover residues of fludioxonil in/on grapes. Residues of fludioxonil in/on grape processed commodities will be covered by the MRL recommended for the raw agricultural commodity (RAC). Residues of fludioxonil in these commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.